AMENDMENT OF SOLICITATION/MODIFIC	CATION OF CONTRACT		1. CONTRACT ID CODE	E OF PAGES			
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQI	UISITION/PURCHASE REQ. NO.	5. PROJEC	CT NO. (If applicable)		
001	10/14/2014	PR-O	RD-14-02715				
6. ISSUED BY CODE		7. ADM	IINISTERED BY (If other than Item 6)	CODE	,		
CPOD US Environmental Protection 26 West Martin Luther King Mail Code: NWD Cincinnati OH 45268							
8. NAME AND ADDRESS OF CONTRACTOR (No., stre	et, county, State and ZIP Code)	(x) 9A.	AMENDMENT OF SOLICITATION NO.				
BATTELLE MEMORIAL INSTITUTE 505 KING AVE COLUMBUS OH 432012693	,	98. X 10A EP	DATED (SEE ITEM 11) MODIFICATION OF CONTRACT/ORDER -C-11-038	NO.			
CODE (b)(4)	FACILITY CODE	 02	2/28/2014				
	11. THIS ITEM ONLY APPLIES	1 1	,,				
separate letter or telegram which includes a reference THE PLACE DESIGNATED FOR THE RECEIPT OF virtue of this amendment you desire to change an off to the solicitation and this amendment, and is received.	pies of the amendment; (b) By acknote to the solicitation and amendment represented by the solicitation and amendment represented by the solicitation of the solicitation of the solicitation of the opening hour and date	owledging recenumbers. FAIL ND DATE SPE nay be made by	pipt of this amendment on each copy of the o LURE OF YOUR ACKNOWLEDGEMENT TO CIFIED MAY RESULT IN REJECTION OF Y	offer submitted O BE RECEIVE OUR OFFER	; or (c) By ED AT If by		
12. ACCOUNTING AND APPROPRIATION DATA (If re	quired) 1	Net Inc	cease: \$	72,014.	00		
See Schedule	IODIFICATION OF CONTRACTOR	DEDO 17.40	DIFIES THE CONTRACT/ORDER NO. AS DI		ITTLE A		
	CT/ORDER IS MODIFIED TO REFL H IN ITEM 14, PURSUANT TO THE NT IS ENTERED INTO PURSUANT	ECT THE ADN AUTHORITY	ES SET FORTH IN ITEM 14 ARE MADE IN MINISTRATIVE CHANGES (such as changes OF FAR 43.103(b). TY OF:				
X Limitation of Funds	Notice	·	,				
E.IMPORTANT: Contractor (A) is not. 14. DESCRIPTION OF AMENDMENT/MODIFICATION Tax ID Number: (b)(4) DUNS Number: The purpose of this modifiat TOPO: Joseph Wood LIST OF CHANGES: Reason for Modification : Fu	ion is to add fund	gs, including so	± 11	ible.)			
Obligated Amount for this Mo	dification: \$72,01						
Except as provided herein, all terms and conditions of the 15A. NAME AND TITLE OF SIGNER (Type or print)	ne document referenced in Item 9A o						
INA. MAINE AIND THEE OF SIGNER (Type of print)			AME AND TITLE OF CONTRACTING OFFI	UER (1ype or	pink)		
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNE		amille W. Davis	ELECTRONIC SIGNATURE			
(Signature of person authorized to sign)		1.0	andre Advisor Andrea	OIMINI AUR	-0/+1/2014		

NSN 7540-01-152-8070 Previous edition unusable STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243
 CONTINUATION SHEET
 REFERENCE NO. OF DOCUMENT BEING CONTINUED
 PAGE
 OF

 EP-C-11-038/0017/001
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NAME OF OFFEROR OR CONTRACTOR

ITEM NO.	SUPPLIES/SERVICES	QUANTITY		UNIT PRICE	AMOUNT
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	To: \$322,014.00				8 0
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	Ending Fiscal Year 15 Fund (Appropriation) C		20		
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c.	Budget (BOC) 2532 Job # (Site/Project)				
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	Durham NC 27703 USA				
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	RTP-Finance Center (D143-02) 109 TW Alexander Drive	.8		e ii	
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02/28/20						a. NAME OF CONSIGNEE									
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3. ORDER NO. 0017	R NO. 4. REQUISITION/REFERENCE NO. PR-ORD-14-00246						US Environmental Protection Agency								
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ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

PAGE NO

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02/28/2		EP-C-11-038		e		0017	J	
ITEM NO.	<u> </u>	SUPPLIES/SERVICES	QUANTITY		UNIT		AMOUNT	QUANTITY
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PERFORMANCE WORK STATEMENT STREAMS II

Task Order 0017, Battelle EP-C-11-038

TITLE: NEUTRALIZATION OF RICIN TOXICITY USING ELEVATED TEMPERATURE AND HUMIDITY

Task Order Contracting Officer Rep	Alternate Task Order COR						
Name: Joseph Wood	Name: Shannon Serre						
Office: ORD/NHSRC	Office: ORD/NHSRC						
Decontamination and Consequence	Decontamination and Consequence						
Management Div.,	Management Div.,						
Research Triangle Park, NC 27711	Research Triangle Park, NC 27711						
Phone: (919) 541-5029	Phone: (919) 541-3817						
Fax: (919) 541-0496	Fax: (919) 541-0496						
Email: Wood.Joe@epa.gov	Email: Serre.Shannon@epa.gov						

PERIOD OF PERFORMANCE: March 3, 2014 through March 3, 2015.

The period of performance may be extended for an additional 12 months pending availability of funding.

SUMMARY OF OBJECTIVES

This work shall provide data on how long ricin remains toxic on different materials under different environmental conditions. Specifically, tests shall be conducted to assess persistence of ricin toxicity as a function of different combinations of temperature and relative humidity.

RELEVANCE

The results of these tests will provide information about how long ricin may remain toxic when exposed to different (e.g., either elevated or lowered) temperatures and RH levels. This information will be useful in determining the conditions in which decontamination may or may not be necessary.

BACKGROUND

The U.S. Environmental Protection Agency (EPA) has the responsibility for protecting human health and the environment from accidental and intentional releases of hazardous and toxic materials. According to Homeland Security Presidential Directive 10 (HSPD-10), the EPA is tasked with developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities following a biological weapons attack. In response to this directive, the EPA Office of Research and Development (ORD) National Homeland Security Research Center's (NHSRC) Decontamination and Consequence Management Division (DCMD) is conducting persistence studies of ricin and other biological agents on materials/surfaces. This work will utilize methods from previous persistence and decontamination studies that have already been conducted by DCMD.

SCOPE

The purpose of the study is to quantify the recovery of ricin from six (6) materials at different elapsed time points when exposed to different combinations of temperature and RH. It is also anticipated that ricin will be tested in both crude and refined forms. The six materials that will be used for testing have not been selected at the writing of this Task Order, but may include both indoor and outdoor types of materials. These materials will be selected in consultation with the TOCOR during the writing of the Quality Assurance Project Plan (QAPP). Fifteen separate tests (15 test durations) shall be conducted. Sufficient replicates, blanks, and positive controls shall be used, consistent with previous EPA and other peer reviewed ricin studies and quality assurance procedures.

Conference calls shall be established on an *ad hoc* basis between the EPA TOCOR and the contractor. During these conference calls the contractor shall report on progress made in the project and any technical issues encountered in implementation of the test plan.

TECHNICAL APPROACH

For each test, the effort shall include the recovery of ricin from each material before (positive control) and after each test duration has been completed. Five (5) replicates for each agent-material-time point combination and five (5) replicates for each agent material positive control shall be included in each experiment.

TASKS

TASK 1: DRAFT A QUALITY ASSURANCE PROJECT PLAN

The contractor shall draft a Quality Assurance Project Plan (QAPP) that shall cover the work outlined in this performance work statement (PWS) including a project timeline. This QAPP shall follow guidelines set forth in Attachment #1 to the PWS. In this plan, the test matrices must include laboratory blanks, positive controls, and procedural blanks in addition to the test coupons. The QAPP shall be submitted to the EPA TOCOR within 30 days after Task Order (T.O.) award, and then revised per TOCOR and the EPA QA Manager comments. No tests shall be conducted until the QAPP has been approved by the EPA QA manager. (All approvals will come over email.) Approval time is usually 2-3 weeks.

All methods, materials, procedures, equipment, ricin preparations and analyses, etc., conducted under this task order, shall be consistent with those used in previous related studies directed by EPA researchers or as documented in peer reviewed journal articles. Examples of two EPA references are EPA 600/R-10/097, Novel Cell-Based Assay for Testing Active Holo-Ricin and Its Application in Detection Following Decontamination; and EPA/600/R-08/002, Impact of Temperature and Humidity on the Persistence on Ricin Toxin and Vaccinia Virus on Indoor Surfaces.

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action; see Attachments #1 and #2. The contractor shall prepare a QAPP in accordance with http://www.epa.gov/quality/qs-docs/r5-final.pdf. For guidance on preparing a research-specific QAPP, the preparer should refer to the project specific requirements provided in NHSRC's QMP. The QAPP shall be approved prior to the start of any laboratory work. Additional information related to QA requirements can be found at www.epa.gov/quality.

TASK 2: PERFORM PERSISTENCE TESTS

The contractor shall conduct experiments to determine the recovery of ricin (using both crude and refined forms) on six (6) materials at 15 non-zero time points (i.e., 15 separate tests). These tests shall be conducted at different combinations of temperature and RH. It is expected that the majority of tests shall be conducted at elevated temperatures (up to 100 degrees F) and RH levels (up to 100 % RH), although a few tests shall be conducted to assess the effect of low temperature (e.g., 30-40 degrees F) and RH (e.g., 20-30%) as well.

Initial test durations and environmental conditions shall be selected in consultation with the TOCOR during the writing of the QAPP, and follow on test durations shall be selected based on results of ongoing tests. Contractors shall base their cost proposal for each test on the expectation that the longest duration tested may be one (1) week (at the low temperature condition).

Five (5) replicate agent-material test coupons and five (5) replicate agent-material positive controls shall be included in each experiment, with a sufficient number of blanks.

Neutralization of ricin toxicity over time shall be determined quantitatively based on the recovery of the agent from the tested coupons and on the positive controls, as described in more detail in the QAPP. The results shall be reported in terms of each time point as well as each environmental condition.

<u>Task 2 Deliverable</u>: Transfer of project data (including raw data) shall occur at the conclusion of each experiment within each task. The data sheets shall also include the experimental conditions (e.g. temperature and relative humidity), the measured agent levels on all of the coupons (test coupons, procedural blanks, positive controls, and laboratory blanks), etc. The subsequent experiments shall not begin until the EPA TOCOR has reviewed and approved the data (1-2 days from receipt of data) from the current task.

TASK 3: REPORT

The contractor shall prepare three (3) drafts of the report.

<u>Task 3 Deliverable #1:</u> The first draft of the report shall be received by the TOCOR no later than three (3) weeks after completion of the final test. The EPA TOCOR will provide comments on the first draft within two (2) weeks after receipt.

<u>Task 3 Deliverable #2</u>: The contractor shall revise the report based on the TOCOR comments within one (1) week of receiving the TOCOR comments. The TOCOR will send the second draft of the report for peer and QA review (which may take three (3) weeks), and then submit the peer and QA comments to the contractor.

<u>Task 3 Deliverable #3</u>: The contractor shall revise the report (prepare the third draft) based on the comments from the peer and QA reviewers, and in consultation with the TOCOR, no later than the final date of this T.O.

<u>Task 3 Deliverable #4</u>: Transfer of project data (including raw data) shall occur at the conclusion of each experiment within each task. The data sheets shall also include the experimental conditions (e.g. temperature and relative humidity), the measured agent levels on all of the coupons (test coupons, procedural blanks, positive controls, and laboratory blanks), etc. The subsequent experiments shall not begin until the EPA TOCOR has reviewed and approved the data (1-2 days from receipt of data) from the current task.

<u>Task 3 Deliverable # 5</u>: A document describing any deviations from the QA plan shall also be provided along with the final report.

REPORTING REQUIREMENTS

- 1. Laboratory data shall be transferred electronically to the EPA TOCOR after the conclusion of each trial or series of tests. All products developed under this PWS (e.g., the above mentioned technical report) must conform to the requirements of EPA/NHSRC's guide to writing research reports found at the following website:

 http://www.epa.gov/nhsrc/pubs/FINAL_PDF_Policy_and_Guidance.pdf
- 2. Prior to submission of the final data package, all of the data shall be given to the EPA TOCOR in electronic format (specifically Microsoft Excel spreadsheets). The data on these spreadsheets shall be straightforward and explanation of the results via comments shall be added if they are not straightforward.
- 3. Copies of internal audit reports and responses shall be sent to the EPA TOCOR in a timely fashion. The TOCOR and EPA Quality Assurance Manager shall be immediately notified of any critical findings.
- 4. The contractor shall document all data analysis including statistical models and related assumptions.

QUALITY ASSURANCE SURVEILLANCE PLAN (QASP) STREAMS II Task Order 0017, Battelle EP-C-11-038

TITLE: NEUTRALIZATION OF RICIN TOXICITY USING ELEVATED TEMPERATURE AND HUMIDITY

TASK ORDER MANAGER – Joseph Wood

Performance Objective (Task)	Performance Standard (PS)	Surveillance Plan (SP)	Contractor Incentive (CI)	<u>✓</u>
Task 1: Draft a Quality Assurance Project Plan	Contractor drafts a quality assurance plan and revises as directed by TOCOR and EPA's Quality Assurance (QA) Manager.	TOCOR and the EPA QA Manager will review the quality assurance plan.	TOCOR will address compliance in PPE	X
Task 2: Perform Persistence Tests	Contractor conducts all tests outlined in the PWS and QAPP. Data are delivered to TOCOR (for example, raw data, agent recoveries, data quality indicators, temperature and relative humidity levels) periodically as indicated in PWS.	TOCOR will document whether receipt of data delivery is complete and timely.	TOCOR will address compliance in PPE	X
Task 3: Report	Contractor completes three (3) drafts of the report. Contractor addresses TOCOR, QA and peer review comments, as outlined in PWS.	TOCOR will provide comments on final report and document that the contractor has addressed all the TOCOR, QA and peer review comments.	TOCOR will address compliance in PPE	X